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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,519	11/01/1999	SHIH CHUNG	AH0948Q	8808

7590

03/18/2002

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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16

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/11/02

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-42 is/are pending in the application.
Of the above, claim(s) 21-42 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-42 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Receipt is acknowledged of Request for time CPA and Associate Power, of 2/11/02 each.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-42 stand withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No 3.

This application contains claims 21-42 stand drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP 821.01.

Claims 1-13, 16, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Deasy.

The rejection of record is maintained.

At column 3, lines 45-48, Deasy states the invention preferably employs anabolic agents, Zeranol, the instant claim 9 compound. At Col 2, we are taught the release rate can be made to vary, as a function of molecular weight of polymers, the amount of active, addition of plasticizers and additives, number of pieces, pressure or heating (lines 26-44). Note applicants inventions at claim 9, fails to specify first or second formulations of zeranol; it can be in either or both, as it can in Deasy cooperating formulations.

Deasy does have more than 2 formulations but the comprising instant language accommodate more. Further, we do not know what "immediate", "First", second" "controlled", "stimulating", "greater", "total weight %" refer to or have as ranges, limits or endpoint as they are all relative terms i.e.- immediate upon injection, upon dissolution of support matrix,

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dissolution of an outer layer metabolism, or what? First-first in line with another as one looks at the composition, or as one injects it? As the outside layer, or the core?

Claim 19 is clear as to weight %, claims 11 and 12 are not. Note that identification of the dosages (it's not evident) of the specific anabolic agents would make the questions of the limitations of the preamble terms "greater growth" etc. moot.

Claims 1-5, 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivy.

The rejection of record is maintained.

Applicant argues Zearalins are not peptides, Ivy discloses Zearalenone at Col 1, line 66-line 20, Col 2. These compounds are derivatives of the Zearlanol, of the instant claims identified as Zeranol (Claim 9, of the instant, and line 17, Col 2 of Ivy) Ivy says these are agents for improving weight gain and feed efficiency. Examiner interprets improving to equal applicant's recitation of "stimulating increased rate of growth", greater amount of growth and greater feed efficiency in cattle", especially since Ivy even identifies the dosage (Claim 2). We find Ivy's ingredients of the 2 components implant to be 2 anabolic agents; because Ivy says so claim 1, lines 3 and 4. Either can be first; both are released. Either can be controlled, both are found to cooperate to permit of lowered bGH than if bGM were used alone (Col 11, lines 1-18. The release of growth hormone is immediate relative to that of the controlled release of Zearalone, in a long acting form (Col 3, line 68 Col 4, line 2) that provides daily (immediate) effective amounts.

Claims 1-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Deasy in view of Ivy et al, O'Callaghan et al, Sivarrrrramakrishnan and Kim et al.

The rejection of record is maintained.

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Applicant's arguments are that none of the references suggest applicant's invention, now characterized as a dual formulation, only one of which consist essentially of an anabolic agent, while the other comprises an anabolic agent and controlled release agent. We fail to find the language to exclude the prior art compositions.

Claims 1-8,13,14,16,17,18-20 are rejected under 35 U.S.C. 102 (b) as anticipated by or in the alternative under 35 U.S.C. 103 (a) as obvious ever Gresser etal WO 93117704.

Gresser provide a first and second, or more (claim 11 system of PLGA polymeric materials (P.5, line 23-36) for implants, as is art recognized. Rate of release are controllable (P.8, line 1-8). Advantages are controlled release instead of multiple injections (p.18), one will do.

Drugs include hormones (claim 8) delivery at different times, (claim 21 shows 2 different compounds) A, B) is shown. Thus, an immediate, then controlled. Hormones include Growth Hormone. Weight ratios of formulations are within those instantly claimed. Wall thickness, thus unit weight, can be adjusted as desired to program the desired release rate of the particular formulation (P.12, Paragraph 1). The particular agents are not constrained, if growth hormone, then the same agent is able to be used in each formulation unit, but growth hormone and somatotropin could be used, in different units. Additives are at P.7 dextrose included.

Claims 1-13, 16,17,19,20 are rejected under 35 U.S.C. 102 b as being anticipated by Lewis 5288496.

See summary: multiple drug (trenbolone acetate and/or zeranol) in lactide/glycolide (Example 8) polymers provides the instant implants (lines 51-55, Col 2) for growth promotions to cattle (line 59, Col 2). Drug to polymer ratio is the instant ratio (Col 3, line 65-line 2, Col4) of instant polymer (col. 4, lines 13-18) with drug dosage known to the artisian (Col. 6 line 28-42).

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The same drug at 2 different formulations is Example 9. Two forms are taught at Claim 6, claim 15. Immediate and prolonged release are attained See Fig. 1, ear injection results in immediate (Day 0) release of Estradiol, with continued release for 120 days. Diluents include carboxyl-cellulose.

Claims 1-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lewis 5288496 and Lee et al 5022554.

Lewis (above) discloses the essence of the instant invention, but not all adjuvant and excipients, as are known in the art identified. But Lee provides similar implants of anabolic growth promoters (Col 9) and states such excipients (i.e. lactose) are well known in the art. Ethyl cellulose is exemplified (Eudragit, Table A).

It would be obvious to a person of ordinary skill in the art at the time the invention was made, desiring to utilize implant compositions to use on of Lewis and /or Lee in a container to permit release when the actives are required with modification, it desired, as taught by Lee to permit of controlling release rate by choice of polymer and with fillers and adjuvants as are art recognized.

There is no-obvious and/or unexpected results obtained since prior art is well aware of the use of polymers binders plasticizers and the use of additives for the functionality for which they are known to be used is not a basis for patentability. The selection of adjuvants is a result effective parameter determinable by artisian as desired for purpose of providing ingredient compatibility and controlled release of drugs.

All the critical elements of the instant invention are disclosed.

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Applicant's arguments filed on 2/11/02 have been fully considered but they are not persuasive. Applicant's arguments have been addressed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to levy Neil whose telephone number is 308-2412. The examiner can normally be reached on Tuesday-Friday from 7:00am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose dees, can be reached on (703) 308-4628 fax-phone number for the organization where this application or proceeding is assigned is 305-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy/dl

March 8, 2002



NEIL S. LEVY
PRIMARY EXAMINER